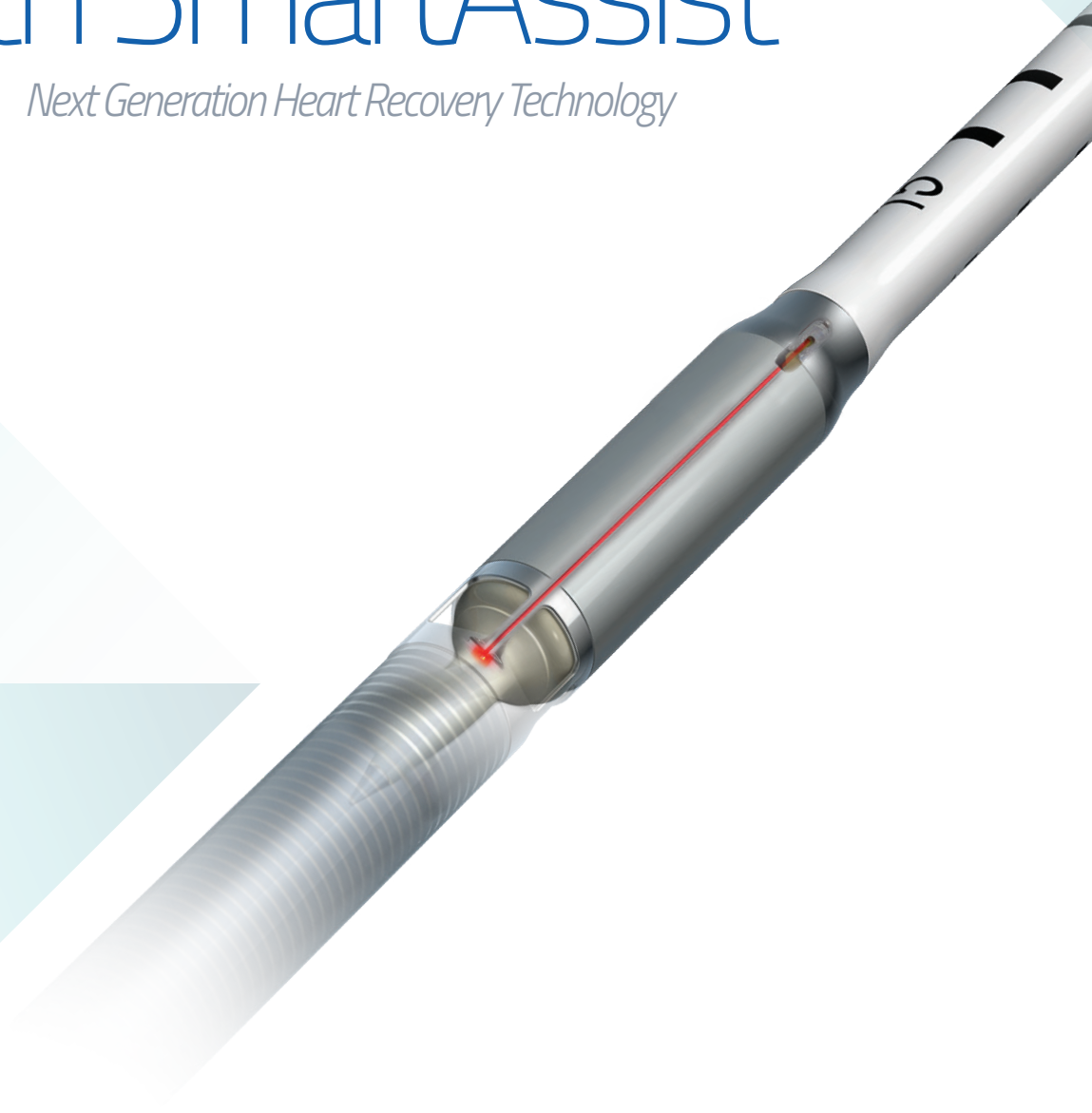


Impella CP[®] with SmartAssist[®]

Next Generation Heart Recovery Technology



Impella® CP with SmartAssist®

The latest innovation on the Impella platform integrates the trusted performance of the Impella CP heart pump with state-of-the-art SmartAssist technology. This next generation heart pump is designed to improve patient outcomes by using real-time intelligence to optimize positioning, managing and weaning of the Impella device for better patient care.



Impella® Heart Pump

Greater hemodynamic support and ease of use. New sensor technology allows for repositioning in the ICU without the need for imaging.*



Advanced Pump Metrics

Intelligent pump metrics on the Automated Impella® Controller assist in positioning, managing and weaning the Impella device.



Impella Connect®

Cloud-based, remote viewing for better patient outcomes.

* For ventricularized pumps

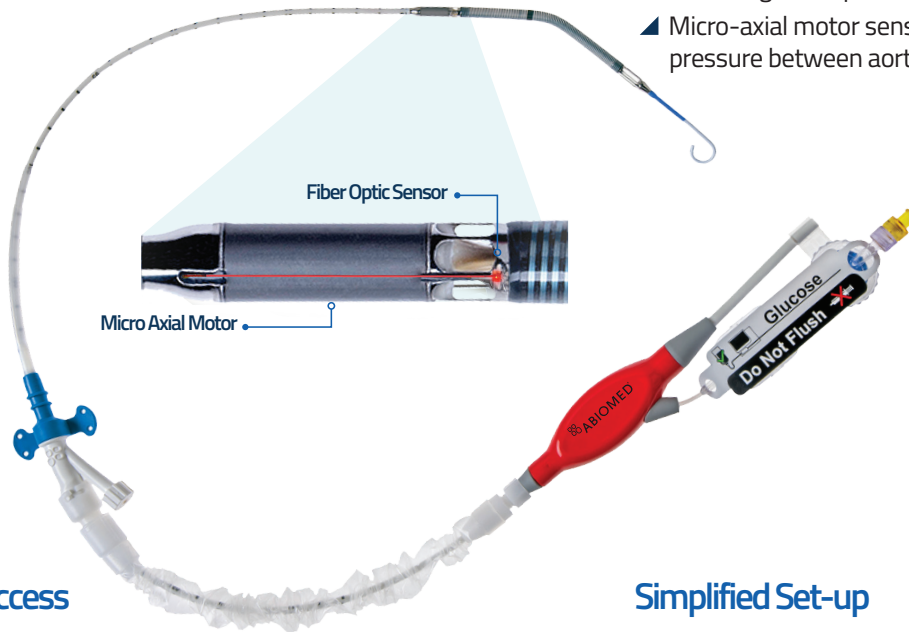
Impella CP with SmartAssist

New Features to Improve Hemodynamic Support and Ease of Use

Greater Hemodynamic Support

Confident positioning allows for sustained higher flows.

- ▲ Peak flows up to 4.3 L/min



Confident Positioning

New hemodynamic sensors assist in managing and positioning Impella CP.

- ▲ Optical sensor senses pressure readings indicating aortic pressure
- ▲ Micro-axial motor senses pressure indicative on pressure between aorta and left ventricle

Maintain Arterial Access

Reaccess sheath allows for escalation of care and is designed to improve hemostasis.

- ▲ Allows access to the artery with up to a 0.035" guidewire
- ▲ 4 cm additional length

Simplified Set-up

Improve ease of use and faster set-up time.

- ▲ Reduction in set-up steps with fewer connections
- ▲ Single fluid line management in ICU



Advanced Pump Metrics

Designed to optimize pump management and assist in weaning

- ▲ Left ventricular placement signal
- ▲ Only percutaneous heart pump that displays Cardiac Power Output
- ▲ Displays trends of LVEDP and MAP to assist weaning
- ▲ 50% reduction in timing to resolve suction event¹

Cardiac Power Output: #1 Correlation to Mortality in AMI Cardiogenic Shock²

- ▲ $CPO \text{ (in watts)} = (MAP \times \text{Cardiac Output}) / 451$

Impella CP[®] Heart Pump Specifications

PART NUMBER	DESCRIPTION
0048-0014	Impella heart pump, 9 Fr catheter, 6 Fr pigtail, 14 Fr micro-axial pump, Percutaneous insertion through the femoral artery
0043-0003	Impella Controller Purge Cassettes, Box of 5
0052-3025	14Fr Combo Introducer Kit containing 13cm and 25cm length sheaths
0052-3005	0.018" x 260 cm PTFE Guidewire for Impella 2.5 and Impella CP

Maximum Flow: 4.3 L/min

Maximum Mean: 3.7 L/min

Speed Range: 0 to 46,000 rpm

Interventional Length: 92-98cm

Learn more visit www.impella.eu/smartassist

LEFT-SIDE SUPPORT

INDICATIONS FOR USE

Impella CP[®] with SmartAssist[®]: The Impella (intracardiac pump for supporting the left ventricle) is intended for clinical use in cardiology and in cardiac surgery for up to 5 days for the following indications, as well as others:

- The Impella is a circulatory support system for patients with reduced left ventricular function, e.g., post-cardiotomy, low output syndrome, cardiogenic shock after acute myocardial infarction, or for myocardial protection after acute myocardial infarction
- The Impella may also be used as a cardiovascular support system during coronary bypass surgery on the beating heart, particularly in patients with limited preoperative ejection fraction with a high risk of postoperative low output syndrome.
- Support during high risk percutaneous coronary intervention (PCI)
- Post PCI

CONTRAINDICATIONS

- Mechanical aortic valves, severe aortic valvular stenosis or valvular regurgitation
- Hematological disorder causing fragility of the blood cells or hemolysis
- Hypertrophic obstructive cardiomyopathy (HOCM)
- Aneurysm or necrotomy or severe anomaly of the ascending aorta and / or the aortic arch
- Mural thrombus in the left ventricle
- Ventricular septal defect (VSD) after myocardial infarction
- Anatomic conditions precluding insertion of the pump
- Other illnesses or therapy requirements precluding use of the pump
- Severe peripheral arterial occlusion disease (PAOD) is a relative contraindication

POSSIBLE COMPLICATIONS

There are risks of complications with every procedure using a blood pump. These include among others:

- Hemolysis
- Bleeding
- Immune reaction
- Embolism, thrombosis
- Vascular injury through to angionecrotomy
- Positioning problems
- Infection and septicemia
- Dislocation of the pump
- Cardiovalvular injuries due to extreme movement of the suction cannula in relation to the cardiac valve or as a result of attachment by suction of the pump to the valve system following incorrect positioning
- Endocardial injuries as a result of attachment of the pump due to suction
- Pump failure, loss of pump components following a defect
- Patient dependency on the pump after use for support

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella devices. For more information please see the Instructions for Use Manual.

Learn more visit: www.abiomed.com/important-safety-information

Advanced Pump Metrics:

PRECAUTIONS

- The pump performance metrics derived from the Impella pump signals are not valid surrogates for monitoring the overall clinical status of the patient and should be used for informational purposes only.
- The pump performance metrics derived from the Impella pump signals are not intended for diagnostic use. All parameters displayed must be verified independently using either a cleared or approved diagnostic device, and must not be used for patient monitoring.

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